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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,438	10/06/2006	Craig L. Felberg	P03264	3176
1200	7590	05/09/2011		
AKIN GUMP STRAUSS HAUER & FELD LLP			EXAMINER	
1111 Louisiana Street			LIPITZ, JEFFREY BRIAN	
44th Floor				
Houston, TX 77002			ART UNIT	PAPER NUMBER
			3769	
			NOTIFICATION DATE	DELIVERY MODE
			05/09/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/550,438

Applicant(s)

FELBERG ET AL.

Examiner

JEFFREY B. LIPITZ

Art Unit

3769

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/18/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/22/2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 1, 6 and 32 are objected to because of the following informalities: The preambles should recite that the method/system/algorithm is for the selection of a "photoablative" treatment plan. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear how a non-customized treatment plan is based on the factors recited in these claims. In fact, Applicant provides no details related to providing a non-customized treatment plan – only customized and semi-customized treatment plans.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 9-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-6 and 9-31, Applicant's algorithm and method are used to select a treatment plan; and yet there is no step of selecting in the body of any of these claims. It is unclear how a method of aiding in selection could be completed without a step of selecting.

Regarding claim 22, this claim recites that the step of "automatically recommending to the user the desired treatment plan". It is unclear how recommendations occur. On what basis are the treatment plans prioritized? What algorithm(s) is used to determine the "best" treatment plan?

Regarding claims 27-31, these claims provide a factor that the treatment plan should be based on. However, it is unclear how these factors influence the treatment plan based on the recited language. Furthermore, it is unclear how to calculate the residual stroma thickness value.

Regarding claims 36-39 and 44-53, these claims are directed to a "system" that is *only* defined as a display and a computer or structural/functional equivalents thereof. It is unclear how these claims further limit the scope of the system; since a computer and a display can be programmed according to show any of the treatment plans. Furthermore, the treatment plans inherently contain a laser ablation shot file, as that is what Applicant has defined a treatment plan (Summary of the Invention and Page 15).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-15, 17, 18, 21-23, 26-31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicant's method and algorithm are non-statutory because they do not affirmatively state in the body of the claims that they are performed on a particular machine or that underlying subject matter undergoes a transformation from one state to another. See *In re Bilski*, 88 USPQ 2d 1385 (2008). The claims directed to methods and algorithms must include the elements that enable them to be performed. Furthermore, the algorithm should be "executable" in the same manner as claims of other inventions directed to software.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-17, 21, 24-26, 32-41, 43, 46-48 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Knopp et al. (6726680), hereinafter Knopp.

Regarding claims 1-3, 5-6, 13, 16, 17, 25, 32-34, 36, 38 and 40, Knopp teaches obtaining diagnostic information, such as topographic and refractive data (Col. 2, Lines 44-67), using this information to determine what types of templates are appropriate for surgery (Col. 10, Lines 61-67; Col. 11, Lines 1-19), which inherently requires classifying the eye (Col. 32, Lines 4-7). These templates are displayed to a user, modified if

needed, selected by the user, saved on a memory storage device and executed to control the surgery (Col. 11, Lines 13-20; Col. 26, Lines 46-67, Col. 30, Lines 54-67; Col. 31, Lines 1-45). Knopp carries out these functions via a user interface (19; Figure 11) and presents data on a display (18; Summary of the Invention and previously cited sections).

Claim 32 recites the "means for receiving a diagnostic input..." and the "means for displaying...", which invoke a 112 6th paragraph interpretation. According to Applicant's disclosure the former is a processor or CPU and the latter a GUI or monitor. Examiner interprets the microprocessor or central computer (16) as the means for receiving and the GUI (18 and 19) as the display means. A microprocessor is operated by software (Col. 31, Lines 1-19).

Regarding claims 7, 8 and 35, Knopp teaches that the laser (87; Figure 10) is engaged by the computer control assembly (16), and that the controller controls the laser to execute the selected template or treatment plan (Col. 31, Lines 20-50).

Regarding claims 9-12, 15, 37 and 51, Knopp teaches that the treatment plan is comprised by treatment parameters (Col. 33, Lines 54-67), which inherently contains spot sizes and placements, and that data such as optical zone dimensions is show to the user and reviewed (Figure 14). These parameters may be modified, which inherently requires user viewing and review (Col. 33, Lines 54-67; Col. 35, Lines 32-55).

Regarding claims 14, 26 and 39, Knopp's invention is at least concerned with the treatment of myopia, hyperopia and astigmatism (Col. 1, Lines 57-61), which include the

lower order aberrations. Each of the templates are chosen as described supra, and customized if desired.

Regarding claims 21 and 43, Knopp teaches using eye-tracking data to determine firing patterns (Col. 3, Lines 40-56; Col. 6, Lines 16-37).

Regarding claims 24, 41 and 47, Knopp teaches using the GUI to set display or presentations options, which inherently include screen headers, as well as to create and or modify templates, which inherently include modification of default values (Col., Lines 47-60).

Regarding claim 46, Knopp teaches providing a screen that contains the tabs "File", "Patient", "Diagnostics", "Treatment", "Utilities" and "System" (Figures 12-14). Examiner interprets this screen when a file is not opened as a start-up navigation screen.

Regarding claim 48, Knopp teaches using video imaging, which requires the viewing of a diagnostic data file, as well as accessing online diagnostic information (Col. Col. 10, Lines 30-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 18, 22, 23, 26-31, 42, 44 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knopp.

Regarding claim 4, Knopp teaches using diagnostic tools to determine the types of astigmatism and other corneal surface data (Col. 32, Lines 47-64). Although Knopp does NOT explicitly discuss classifying according to the three categories recited, it is well known in the art to use corneal topographical data to determine whether an eye is myopic or hyperopic, and the degree of astigmatism. In fact, in order to treat eyes with astigmatism, this classification would be inherent. It would have been obvious at the time the invention was made to classify the eye as myopic or hyperopic with or without astigmatism, because doing so would have enabled the proper planning of an ablation treatment plan to correct the ocular disorder.

Regarding claims 18, 22 and 44, Knopp teaches providing a library of templates that correspond to different surgical procedures. The user then chooses between the templates drawing on previous experiences with them. Knopp does NOT teach that the system provides an automatic recommendation. However, since Knopp does teach that a group of pre-existing templates are provided, and that the user must choose between them, the programming that would have been required to prioritize the templates would have been an automation of the existing methods. It would have been obvious to provide a function that automatically ranks the templates, and or provide the best template to the user according to user preferences, because doing so would have reduced the amount of time spent manually reviewing the group of templates provided for a given procedure.

Regarding claim 23, Knopp discloses that the user may choose from pre-existing templates and resize/rescale the prescription to match the particular patient (Col. 11, Lines 13-20). Examiner interprets the resizing/rescaling as identifying limit parameters, which obviously would have been used to determine which treatment plans are viable. It would have been obvious to select viable treatment plans in this manner because doing so is based on treatment plans that have been shown to be successful in obtaining their desired outcome.

Regarding claims 26-31, Applicant recites factors that could be used to provide non-customized treatment plans. The relationship between these factors and potential factors must be known in the art, since Applicant provides no connection between the factors and the plans. In addition, these claims recite limitations that are not critical or essential to the practice of the invention. They merely represent obvious design choices that would have been obvious to provide because skilled artisans have previously used these factors at least in part to design treatment plans.

Regarding claim 42, Knopp does NOT specify the storage device. However, Examiner takes official notice that the use of a computer hard drive, a floppy disk, a CD, and a DVD for that purpose was well known to skilled artisans at the time the invention was made.

Regarding claim 52, Knopp teaches comparing two treatment plans (Col. 11, Lines 50-65); however, he does NOT specify providing them both simultaneously on a screen for comparison. However, it would have been obvious for a skilled artisan to

enable simultaneous viewing, because it would have enabled a user to directly compare each of the treatments parameter by parameter to assess the viability of the treatments.

Claims 19, 20, 45, 50 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knopp as applied to claims 16, 32 and 41 above, and further in view of Frey et al. (20010041884), hereinafter Frey.

Regarding claims 19, 20, 45, 50 and 53, Knopp does NOT teach a screen containing information such as patient identification data used for review. Attention is directed to Frey teaches who teaches using a laser surgery to correct vision (Abstract). Frey teaches providing a patient information data screen for review (Paragraph [0174]). It would have been obvious to modify Knopp to include the patient information data screen because doing so would reduce the chances of performing the wrong procedure on patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571)272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEFFREY B LIPITZ/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Primary Examiner, Art Unit 3769